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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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EXAMINER

ART UNIT	PAPER NUMBER
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9

DATE MAILED:

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/647,705

Applicant(s)

SAKAMOTO, KENJI

Examiner

Suryaprabha Chunduru

Art Unit

1656

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 November 2000.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) 5-17 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 18) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: _____

DETAILED ACTION

1. The Information Disclosure Statement (Paper No. 6) filed on February 21, 2001 and the Preliminary Amendment/ response to restriction (Paper No. 8) filed on May 18, 2001 have been entered and considered.
2. Applicant's election of claims 1-4 in Group I without traverse is acknowledged. Original claims were 1-17. Claims 5-17 are withdrawn. Claims 1-4 are considered for examination in this office action.
3. Claim 1 is objected to because of the following informalities: the word "cell" is misspelled. Appropriate correction is required.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 2 is rejected under 35U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 2 is drawn to a method of producing physiologically active peptides or its derivatives. The specification discloses a method for producing physiologically active peptides. Claim 2 meets the written description provision of 35 USC 112, first paragraph because large Genus (its derivatives) is represented in the claim 2. Thus, applicant has expressed possession of only one species in a genus which comprises hundreds of millions of different possibilities.

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The written description guidelines note regarding such genus/species situations that "Satisfactory disclosure of a 'representative number' depends on whether one of skill in the art would recognize that the applicant was in possession of the necessary common attributes or features of the elements possessed by the members of the genus in view of the species disclosed." (See: Federal Register: December 21, 1999 (Volume 64, Number 244), revised guidelines for written description). The specification provides insufficient written description to support the method of producing derivatives of active peptides. Further no information is given regarding a methodology to determine such common elements or attributes.

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed*." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116).

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 1 and the dependent claims 2-4 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 1 is confusing for referring to the subject matter "examining a receptor". Thus it is unclear how the receptor being examined or what the word 'examining' accomplishes for.

Claim Rejections - 35 USC § 102

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6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Song et al. (Proc. Natl. Acad. Sci. USA., 90: 9085-9089, 1993).

Song et al. teach a method for human gastrin/cholecystokinin type B (CCK_B) receptor gene variants having two sizes short and longer isoforms (see page 9087, paragraph 2). Song et al. disclose that the method involves examining CCK_B receptor gene mRNA variants by comparing sequence of longer and shorter isoform in which the shorter isoform lacks a pentapeptide sequence (missing region) that is present in the longer isoform (see page 9088, lines 1-14). Song et al. also disclose the cDNA sequence analysis of gastrin/CCK_B receptor isoforms (see page 9088, Fig. 4). Further, Song et al. discloses that the missing region, the penta peptide sequences cassette in gastrin/ CCK_B receptor may be of potential functional importance. Thus the disclosure of Song et al. meets the limitations in the claim 1.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Song et al (Proc.Natl.Acad.Sci.USA., 90: 9085-9089, 1993) and in view of Naranda et al. (Proc.Natl.Acad.Sci.USA., 94: 11692-11697, 1997).

Song et al. teach a method for human gastrin/cholecystokinin type B (CCK_B) receptor gene variants having two sizes short and longer isoforms (see page 9087, paragraph 2). Song et al. disclose that the method involves examining CCK_B receptor gene mRNA variants by comparing sequence of longer and shorter isoform in which the shorter isoform lacks a pentapeptide sequence (missing region) that is present in the longer isoform (see page 9088, lines 1-14). Further Song et al. disclose the cDNA sequence analysis of gastrin/CCK_B receptor isoforms (see page 9088, Fig. 4). However, Song et al. did not teach the physiological activity or biological activity of the receptor variants and receptor antagonists.

Naranda et al. teach bioactivity of insulin receptor (IR) variant (MHC-I peptide) and its antagonist property (see page 11692, paragraph 2). Naranda et al. disclose that IR peptides having sequence similarity with MHC-I peptide or shorter version (IR_p (trunc)) synthesized chemically and were analyzed for their bioactivity (see page 11693, paragraph 1 and 4). Naranda et al. disclose that the bioactivity was examined for the IR peptides by comparing their effects on ligand-induced internalization in CHO cells overexpressing each receptor (see page 11695, paragraph 2).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the method of identifying human gastrin/CCK_B receptor variants as taught by Song et al. with bioactivity assay as taught by Naranda et al. because Song et al. states that "the two receptor isoforms may contribute to functional differences in gastrin-and

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CCK-mediated signal transduction". One such functional attribute, expressly motivated by Naranda et al. is the delineation of bioactivity of receptor variants "for identifying receptor-specific sites of importance for receptor-specific sites of importance for receptor internalization, and for enhancing sensitivity to hormones and other agonists". An ordinary practitioner would have been motivated to analyze active peptides of different sizes of the receptor, because Naranda et al. thought that they may enhance sensitivity to agonists, to use the method for identifying biologically active receptor peptides.

No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suryaprabha Chunduru whose telephone number is 703-305-1004. The examiner can normally be reached on 8.30A.M. - 4.30P.M, Mon - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones can be reached on 703-308-1152. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-0294 for regular communications and - for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Suryaprabha Chunduru
May 31, 2001



JEFFREY FREDMAN
PRIMARY EXAMINER